REMARKS

Claim Status

Claims 1-10 and 19 have been canceled without prejudice.

New Claim 21 has been added based on the description at page 26, lines 15-19.

New Claim 22 has been added based on Examples VII and VIII on page 24.

New Claims 23 and 24 have been added based on original Claim 11.

New Claim 25 has been added based on original Claim 2.

Claims 11-18 and 20-25 are now pending in the present application.

Claim 11 has been amended based on Examples II-V and VII-IX at page 24.

Claim 14 has been amended to delete the phrase "and derivatives thereof".

Information Disclosure Statement

Applicants have submitted via an Information Disclosure Statement ("IDS") a copy of the International Search Report ("ISR") from the PCT application related to the present US application (WO 03/028776 A1). Applicants have also submitted via an IDS the individual references cited in the ISR. It appears that the Examiner has not considered the ISR document itself, but has considered the individual references from the ISR which Applicants have submitted. Applicants do not understand the Examiner's assertion that "a search report is not a non-patent literature." In any event, it appears that the references cited in the ISR have been considered by the Examiner, as indicated by the Examiner's initials next to the references on the Applicant's previously submitted IDS's.

Rejection Under 35 U.S.C. §112

Claims 1-20 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to distinctly claim the invention. Applicants respectfully traverse this rejection. The Office Action asserts that the terms "from about", "at least about", and "less than about" are not defined in the claim and the specification does not provide a

standard for ascertaining the requisite degree and one skilled in the art would not be reasonably apprised of the scope of the invention. Applicants point out that such claim terms are commonly used in defining numerical ranges, especially in the chemical arts. Applicants submit that one of ordinary skill in the art would understand the scope of the invention from these claim terms based on the common use of these terms in claim drafting, the nature of chemical inventions, and the specification of the present invention. Applicants therefore submit that this rejection should be withdrawn.

Claims 1-10 and 19-20 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite because Claim 1 recites "a solid skin treatment agent" and Claim 2 recites "a skin care agent". Claims 1-10 and 19 have been canceled without prejudice and Claim 20 depends from Claim 11. Applicants therefore submit that this rejection is moot and should be withdrawn.

Claims 5 and 14 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action asserts that Applicants have not provided a description of the structure of a representative number of derivative compounds of vitamin C. Applicants have canceled Claim 5 without prejudice. Applicants have amended Claim 14 to remove derivatives of vitamin C from the Markush group of skin treatment actives. Applicants therefore submit that this rejection is now moot and should be withdrawn.

Claims 2, 5, and 14 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse this rejection. The Office Action asserts that derivatives of chitosan and guanidinobenzoic acid are not supported by the specification because incorporation of essential materials by reference to an unpublished US application, foreign application or patent, or to a publication is improper. With respect to chitosan derivatives, Applicants incorporated by reference the description of chitosan materials from WO 01/180911 (note that this should have read WO 01/80911, due to a typographical error), WO 01/80912, WO 01/80913, WO 01/80914, WO 01/80915, and WO 03/30952. Applicants have amended the specification to recite the published US patent applications which correspond to the referenced PCT published applications. Applicants therefore submit that the claim term "chitosan derivative" is properly supported by the specification and meets the written description requirement of 35 U.S.C. §112, first paragraph.

With respect to guianidinobenzoic acid and its salts and derivatives, Applicants have incorporated by reference the description of these materials from US 5,376,655. The incorporation by reference statement can be found at page 27, lines 22-24. Applicants therefore submit that the claim term "guianidinobenzoic acid and its salts and derivatives" is properly supported by the specification and meets the written description requirement of 35 U.S.C. §112, first paragraph.

Obviousness-Type Double Patenting Rejection

Claims 1, 5, 11, 14, 19 and 20 have been provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over Claims 1-22 of US Application Serial No. 10/992,383. Once patentable subject matter has been otherwise identified, Applicants will consider submitting any necessary Terminal Disclaimers to obviate any remaining obviousness-type double patenting rejections.

Rejection Under 35 USC § 103(a)

Claims 1-20 have been rejected under 35 U.S.C. §103(a) as being obvious over Osborn, III et al. (US 6,409,713) taken with Lin (US 2002/0115968) in view of Gatto et al. (US 6,793,930) and Roe et al. (US 6,703,536). Applicants respectfully traverse this rejection.

The presently claimed invention relates to a method of preparing a niacinamide-containing lotion for reliable high speed processing onto a substrate. Applicants have found that the steps and conditions under which the lotion is produced can affect the ability to reliably apply the lotion to a substrate on a high speed processing line. Applicants have found that preparing and applying a lotion in accordance with the claimed invention can avoid problems with clogging equipment used to apply the lotion to the substrates, which can reduce process reliability and efficiency. Applicants describe these benefits of the presently claimed invention in the specification at page 26, line 15 to page 27, line 16.

Osborn, III et al. do not teach or suggest a lotion comprising niacinamide. Osborn, III et al. therefore do not disclose or suggest premixing niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at

least about 35°C, and then milling the premix into a carrier system at a temperature of at least about 35°C until the average droplet diameter of the dispersed premix is less than about 100 microns. Indeed, Osborn, III et al. teach nothing with respect to the order of addition of the ingredients, the temperature under which the ingredients are mixed together, or the desired droplet size of the ingredients and/or resulting emollient composition.

Lin et al. do not disclose or suggest a lotion comprising niacinamide. Lin et al. therefore do not disclose or suggest premixing niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at least about 35°C, and then milling the premix into a carrier system at a temperature of at least about 35°C until the average droplet diameter of the dispersed premix is less than about 100 microns. Lin et al. disclose an absorbing article comprising a substrate having absorbing ability for liquid and powder, and an augmentation layer made of chitosan and added to the substrate. Lin et al., however, do not disclose or suggest combining a chitosan material with niacinamide in a solvent and with a carrier system under the process conditions as presently claimed.

Gatto et al. do not teach or suggest a lotion comprising niacinamide. Gatto et al. therefore do not disclose or suggest premixing niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at least about 35°C, and then milling the premix into a carrier system at a temperature of at least about 35°C until the average droplet diameter of the dispersed premix is less than about 100 microns. Gatto et al. do teach a desirability for particle sizes less than 1000 microns and preferably less than 100 microns, but do not recognize the benefit of reducing the clogging of equipment in a high speed process line upon spraying, extruding or slot coating the composition onto a substrate, especially with respect to a niacinamide-containing lotion.

Roe et al. do not teach or suggest a lotion comprising niacinamide. Roe et al. therefore do not disclose or suggest premixing niacinamide with a material selected from the group consisting of glycerin, propylene glycol, panthenol, and mixtures thereof to form a premix, mixing the premix with a carrier system at a temperature of at least about

35°C, and then milling the premix into a carrier system at a temperature of at least about 35°C until the average droplet diameter of the dispersed premix is less than about 100 microns. Indeed, Roe et al. teach nothing with respect to the order of addition of the ingredients, the temperature under which the ingredients are mixed together, or the desired droplet size of the ingredients and/or resulting emollient composition.

Since the cited references, alone or in combination, do not teach or suggest the elements of the presently claimed invention, Applicants submit that Claims 1-20 are patentable under 35 U.S.C. §103(a) over Osborn, III et al. taken with Lin in view of Gatto et al. and Roe et al.

Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied references. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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